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| 10/814,674      | 03/30/2004  | Ulrika Andersson     | Strom. 7553         | 8291             |

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EXAMINER

BARNHART, LORA ELIZABETH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/814,674

Applicant(s)

ANDERSSON ET AL.

Examiner

Lora E. Barnhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 3-16 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

8.0.0.

### **DETAILED ACTION**

The examiner notes the amendments to claims 1, 4, 5, 11, and 12; the cancellation of claim 2; and the addition of claims 14-16. The examiner agrees that the new claims are supported by the claims examined in the first Office action and that no new matter was added by the amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Claims 1 and 3-16 are currently under examination.

### ***Oath/Declaration***

As was noted on the first Office action, the oath or declaration is defective because it does not identify the mailing address of each inventor. A new oath or declaration is required. See M.P.E.P. §§ 602.01 and 602.02.

### ***Specification***

As was pointed out on the first Office action, the abstract for the application is unacceptable for numerous reasons. The abstract should be **amended** to include that which is new in the art to which the invention pertains. The abstract should not refer to purported merits or speculative applications of the invention. The abstract should be in narrative form and consist of at least 50 (but no more than 150) words. The abstract should be free of legal phraseology, and it should avoid using phrases that can be implied. A **new** abstract is required.

***Claim Objections***

Claim 14 should be amended to add a comma after "LDH" at line 2.

Claim 16 should be amended to recite, "... temperature is between 27.7°C and 30°C."

***Claim Rejections - 35 USC § 101***

The rejection of claim 1 under 35 U.S.C. § 101 is withdrawn in light of the claim amendments.

Claims 3, 4, 13, and 14 are/remain rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See, for example, *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See M.P.E.P. 2175.05(q).

***Claim Rejections - 35 USC § 112***

Claims 1 and 3-16 are/remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and further below. The invention appears to employ novel biological materials, specifically *L. lactis* spp. *lactis* 19435, DSM 14489 and TMB5003.

Applicant may have made the necessary deposit under the Budapest Treaty, but no affidavit regarding public availability has been made of record. M.P.E.P. §2410.01

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reads, "The mere indication that a deposit has been made under conditions prescribed by the Budapest Treaty would satisfy all conditions of these regulations **except** the requirement that all restrictions on access be removed on grant of the patent." *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

The applicant is required to submit an affidavit or declaration, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty **and** that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

Claims 1 and 3-16 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and further below.

Claim 1 compares production by two strains of bacteria, but provides no conditions under which said comparison could be made. Applicant alleges that the applicant tested the two strains under the same conditions as each other, otherwise "the comparison wouldn't be possible and none of the claims in the application would have been able to be included." The examiner agrees that conducting experiments under controlled conditions is good scientific practice, but the fact remains that no basis or conditions for comparison are recited in the **claims**. It is not clear whether the strain of the invention compares as claimed to the 19435 strain under every possible set of conditions. Culture conditions are effective variables that directly affect the production and growth of cultures; therefore, in order to fully describe the instant mutant in terms of

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its activity compared with that of the 19435 strain, applicant must disclose at which *optimized* conditions the cultures were maintained/carried out, as not all conditions would produce the same results; for example, cells at absolute zero produce no lactate, regardless of species and strain identity. Clarification is required. Because claims 3-16 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claims 3, 4, 13, and 14 provide for the use of *L. lactis* spp. *lactis* TMB5003, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, at page 6, paragraph 2 of the first Office action is withdrawn in light of amendments to the claims.

The rejection of claims 5-12 under 35 U.S.C. 112, second paragraph, at page 6, paragraph 3 of the first Office action is withdrawn in light of amendments to the claims.

The rejection of claims 11 and 12 under 35 U.S.C. 112, second paragraph, at page 6, paragraph 4 of the first Office action is withdrawn in light of amendments to the claims.

Claim 15 is confusing in that it recites a pH of "6-7". It is not clear if this phrase means "between 6 and 7" or "-1". Clarification is required.

***Claim Rejections - 35 USC § 102***

Claims 1 and 3-16 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Sjoberg et al. taken in light of Picataggio et al.

The claims are directed to mutant of *L. lactis* spp. *lactis* TMB5003, which produces lactate and lactate dehydrogenase at high levels compared to *L. lactis* spp. *lactis* 19435. Some dependent claims recite a method for producing lactate comprising cultivating TMB5003. In some dependent claims, TMB5003 is grown in a glucose-containing medium at specific pH and temperature conditions and with specific rates of glucose addition. Some dependent claims recite intended uses for the lactate or lactate dehydrogenase produced by TMB2003.

Sjoberg et al. disclose *L. lactis* spp. *lactis* AS 211, which exhibits increased production of lactate compared to *L. lactis* spp. *lactis* 19435 (Figure 2). Sjoberg et al. also disclose that L-lactate dehydrogenase (LDH) catalyzes the formation of L-lactate from pyruvate; therefore, a strain producing increased lactate must also produce increased lactate dehydrogenase (Figure 1). The medium of Sjoberg et al. comprises unlimited glucose fed at a dilution rate ranging from 0.60-0.85 (Figure 2B). The incubations of Sjoberg et al. were carried out at 30°C (p.932, column 1). WO '842 is cited as evidence that lactate is useful in many fields, including medicine and food processing (p.1, lines 16-17).

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' TMB5003 strain differs and, if so, to what extent from the AS211 strain discussed in Sjoberg et al. Accordingly, it has been

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established that the prior art strain, which has the same genus and species classification and shares the property of being able to produce lactate and lactate dehydrogenase, demonstrate a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by **objective evidence** is shifted to applicants.

Merely because a characteristic of a known strain is not disclosed in a reference does not make the known strain patentable. The AS211 strain possesses inherent characteristics which might not be displayed in the tests used in Sjoberg et al. Clear evidence that the AS211 strains of the cited prior art do not possess a critical characteristic that is possessed by the claimed TMB5003 strain, would advance prosecution and might permit allowance of claims to applicants' TMB5003 strain.

Applicant asserts that the examiner assumed that the 19435 strain is identical to the instantly claimed TMB5003 strain. Applicant also alleges that the AS211 strain of Sjoberg et al. "has a lactate yield improvement of about 20-25%". Finally, applicant has queried the use of the Picataggio et al. reference. These arguments have been carefully considered, but they are not persuasive. For the record, "TMV5003" at page 7, paragraph 5, line 2 of the remarks has been interpreted as reading "TMB5003", in accordance with the specification and claims.

First, the examiner wishes to clarify that the 19435 strain was never assumed to be identical to the instant TMB5003 strain, but rather that the AS211 strain of Sjoberg et al. exhibits increased productivity **compared with** the 19435 strain. The examiner has



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implied that the AS211 strain of Sjoberg et al. may be the same strain as that instantly claimed.

The examiner does not concede the accuracy of applicant's allegations regarding yield improvement, since the applicant has not referenced any particular data points from Sjoberg et al. In any case, the conditions under which AS211 was compared with 19435 in Sjoberg et al. may not be the same conditions under which TMB5003 was compared with 19435 in the instant disclosure, so absent substantive evidence to the contrary, the AS211 strain of Sjoberg et al. is not patentably distinct from the instantly claimed TMB5003 strain.

Finally, regarding the reference to Picataggio et al., two-reference rejections under 35 U.S.C. § 102 are proper under three specific conditions. A 35 U.S.C. § 102 rejection over multiple references has been held to be proper when the extra references are cited to prove the primary reference contains an "enabled disclosure; to explain the meaning of a term used in the primary reference; or to show that a characteristic not disclosed in the reference is inherent. In this case, Picataggio et al. is cited as evidence solely of the numerous industrial applications of lactate. See M.P.E.P. § 2131.01.

***No claims are allowed. No claims are free of the art.***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

le b  
Lora E Barnhart

SANDRA E. SAUCIER  
PRIMARY EXAMINER  
